SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

Device Generic Name:	Total Hip System, Ceramic Articulation
Device Trade Name:	C^2a-Taper™ Acetabular System
Applicant's name and address:	Biomet Manufacturing Corporation 56 East Bell Drive P.O. Box 587 Warsaw, Indiana 46582 US
Premarket Approval (PMA) Number:	P050009
Date of Panel Recommendation:	None
Date of Notice of Approval to the Applicant:	December 16, 2005

The approval of the C^2a - Taper™ Acetabular System is being granted in part due to a licensing agreement with the CeramTec, who owns the rights to the PMA for the TRANSCEND ceramic hip system (P010001). The C^2a - Taper™ Acetabular System uses the same ceramic heads and ceramic liners as the TRANSCEND system while employing Biomet's own acetabular shells and femoral stems. A component comparison along with pre-clinical test results were used to demonstrate that the Biomet C^2a - Taper™ Acetabular System is similar enough to the TRANSCEND system such that the clinical data referenced can be used to predict the clinical outcome of the C^2a - Taper™ Acetabular System.

II. INDICATIONS FOR USE

The C^2a-Taper™ Acetabular System is indicated for use in primary total hip arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and post-traumatic arthritis.

III. CONTRAINDICATIONS

- Local and distant foci of infection
- Skeletally immature patients
- Osteoporosis
- Metabolic disorder, which may impair bone formation
- Osteomalacia

- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
- Vascular insufficiency, muscular atrophy, or neuromuscular disease.

IV. WARNINGS & PRECAUTIONS

Please reference the C^2a-Taper™ Acetabular System physician's labeling to find the warnings and precautions.

V. DEVICE DESCRIPTION

The C^2a-Taper™ Acetabular System is a ceramic on ceramic hip articulating system. The bearing surfaces consist of ceramic femoral heads and acetabular liners. Both components are made of aluminum oxide manufactured by CeramTec AG.

The ceramic femoral heads and acetabular liners are intended to be used in conjunction with Biomet's legally marketed (U.S.) titanium acetabular shells, acetabular screws, and titanium alloy femoral stem designs with a 12/14 taper.

Acetabular Liners
The ceramic liners are available in 28mm and 32mm inside diameter (I.D.) sizes, which correspond to 37mm and 41mm outer diameter tapers, respectively. The 28mm liner is used with 48mm and 50mm shells. The 32mm liner is used with shells ranging in size from 52-70mm in 2mm increments.

Acetabular Shells
The titanium alloy shells are designed with four fins and the outer surface is covered with a plasma sprayed porous coating of titanium alloy (Ti-6Al-4V) powder conforming to ASTM F 1580 (Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants). The shells are available in two taper diameters: 37 and 41mm. The size 37mm taper is available in two outer diameters: 48 and 50mm. The size 41mm taper is available in 48-70mm diameters in 2 mm increments.

Acetabular Screws
Titanium alloy screws in 6.5mm diameters are available for optional supplemental fixation. The 6.5mm dome screws are available in 15-70mm lengths.

Femoral Heads
The 28mm and 32mm ceramic heads are available in three neck sizes: short, medium, and long. The short neck is equivalent to a –3.5mm or – 4mm (depending on head diameter 28 and 32, respectively). The medium neck length is equivalent to standard heads (0mm), and the long neck is equivalent to a +3.5mm or a +4mm head (depending on head diameter 28 and 32, respectively).

Femoral Stems

The titanium alloy 12/14 Taperloc® femoral stems in either a standard or lateralized design are partially porous coated with titanium alloy (Ti-6Al-4V) powder conforming to ASTM F 1580. The stems range in diameters from 5-25 mm and in lengths from 130-170 mm.

VI. ALTERNATIVE PRACTICES AND PROCEEDURES

Depending on individual circumstances, alternative procedures may include the use of other commercially available total hip replacement implants, non-surgical treatment such as reduced activity and /or pain medication, or other surgical treatments that do not involve the use of an implant such as hip joint fusion. Other bearing surface alternatives used in total hip replacement include: ceramic on polyethylene, metal on metal, and metal on polyethylene bearing articulations.

VII. MARKING HISTORY

Biomet France, a subsidiary of Biomet Inc., has marketed a similar system (Eternity) in France since September 1999 using the same ceramic heads and liners. This is the only country in which Biomet Inc. has marketed these ceramic head and liners. These devices have not been withdrawn from marketing for any reason related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS

The C^2a - Taper^{TM} Acetabular System is similar to a previously approved ceramic hip system (TRANSEND, P010001.) C^2a - Taper^{TM} Acetabular System references clinical data from P010001, under a licensing agreement, as clinical support for the C^2a - Taper^{TM} Acetabular System. The clinical data are relevant because the ceramic acetabular inserts of the C^2a - Taper^{TM} Acetabular System are identical to the ceramic acetabular inserts of the previously approved system (P010001) and the ceramic femoral heads of the C^2a - Taper^{TM} Acetabular System are identical to the ceramic femoral heads of the previously approved system (same articulating surface). The two hip systems yielded similar results on the bench.

Please refer to Table 1 - Adverse Events in Section X (Summary of Clinical Investigations) for a tabulation of reported adverse events that occurred in the referenced study (P0100001).

Potential adverse events associated with Any Total Hip Arthroplasty

1. Excessive wear of the ceramic components secondary to damage of mating wear surfaces or debris particles;
2. Although rare, metal sensitivity reactions in patients following joint replacement have been reported;
3. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts;
4. Possible detachment of the porous coating, which could lead to increased debris particles;
5. Pain;
6. Femoral or acetabular perforation, or bone fracture while seating the device;
7. Damage to blood vessels resulting in hematoma;
8. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
9. Undesirable shortening or lengthening of the limb;
10. Traumatic arthrosis of the hip from intraoperative positioning of the extremity;
11. Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
12. Temporary or permanent neuropathies;
13. Delayed wound healing;
14. Infection;
15. Migration, loosening, subluxation, or dislocation of the prosthesis;
16. Periarticular calcification or ossification, with or without impediment to joint mobility;
17. Inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification; and
18. Death.

Potential adverse events associated with C^2a- Taper™ Acetabular System

1. Wear of the alumina ceramic articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris that can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
3. Component dissociation can occur.
4. Breakage of the femoral head or acetabular insert can occur.

IX. SUMMARY OF PRE-CLINICAL INVESTIGATIONS

The C^2a - Taper™ Acetabular System has been found to be similar on the bench (functionally equivalent) to the CeramTec TRANSCEND ceramic hip system (P010001). The C^2a - Taper™ Acetabular System uses the same ceramic balls

and liners as the TRANSCEND system and uses Biomet's own Taperloc stems and Acetabular cups to comprise the system. The comparability of the C^2a-Taper™ Acetabular System and the TRANSCEND systems was demonstrated through a plethora of side-by-side physical comparisons and testing, and has been found to be similar on the bench.

The following pre-clinical studies were conducted on the C^2a-Taper™ Acetabular System. All test results were determined to be sufficient for the intended use of these ceramic on ceramic articulating bearings.

Wear Test

Wear test data performed on the C^2a- Taper™ Acetabular System utilizing the exact same ceramic heads and liners was provided by CeramTec AG. Please refer to the Summary of Safety and Effectiveness data for P010001 for the wear testing details.

Ceramic Femoral Heads Testing

A. Ultimate Compressive Strength

Size 28mm and 32mm femoral heads were tested. Testing used a 100° included angle steel cone for applying the load to the ball head, as described in ISO 7206-10 (Implants for surgery -- Partial and total hip joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads), which has superseded the ISO 7206-5(Implants for surgery-Partial and total hip joint prostheses Part 5: Determination of resistence to static load of head and neck region of stemmed femoral components) standard referenced in the FDA guidance document. The load was applied slowly until the head fractured.

Pass/Fail Criteria

In accordance with "FDA Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" dated January 10, 1995 each femoral head passed with an average fracture strength greater than 46kN. In addition, no ball head fractured at a stress of less than 20kN and, therefore, all passed this test.

B. Fatigue Strength

Femoral Heads with the highest stress for each ball head diameter (i.e. longest neck) based on the ultimate compressive (static burst) strength results were tested. The components that break at the lowest load in the static burst test have the highest stress. A minimum of five (5) ball heads with the longest neck length from each ball head diameter were tested. This includes the 28L and the 32L.

Ti-6Al-4V test tapers were used for each test. The components were

tested with a sinusoidal load of 1.4-14kN for 10 million cycles at a maximum rate of 25Hz or until fracture. All components survived after 10 million cycles and were tested for residual strength by applying an axial load until fracture. Testing parameters used were per the following FDA draft guidance document.

Pass/Fail Criteria
In accordance with FDA Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems, components showed no evidence of cracking or fracture after 10 million cycles and the post-fatigue static compression strengths exceeded 20 kN.

C. **Taper Pull-off Test**

The longest neck lengths (28L & 32L) were tested because they have the least area of contact between the Ti-6Al-4V taper and the ceramic femoral ball head and represent the worst case testing. Five (5) ball heads were tested for both the 28L and the 32L.

Ti-6Al-4V test tapers were used for each test. The ceramic ball head was pre-loaded in compression onto the metal taper using 2 kN installation force. The pull-off required to separate the ceramic head from the metal taper was recorded.

Pass/Fail Criteria
The pull-off strength exceeded 0.2 kN for a 2kN installation force. Currently no minimum strength requirement has been established for this test.

Ceramic Liners Testing

D. **Torsion Strength**

28mm and 32mm liners were tested. The smallest shell sizes (48/37mm for the 28mm liners and 52/41mm for the 32mm liners) were used for testing. This is the worst case condition for testing because these devices have the least taper surface contact area within this acetabular system.

The ceramic liner inserts were pressed into a metal back shell with an axial load of 2kN. A metal ball head was glued into the insert. A lever arm approximately 40mm in length was used to transform an axial force into a torque. The test used a nominal feed rate of 2mm/min. Load on the lever arm was monitored and transformed into torque on the insert. The torque required to cause the insert to slip was recorded.

Pass/Fail Criteria
Torsional strengths exceeded a minimum value of 4 Nm, which is an upper bound estimate of the maximum torque that could conceivably

occur in vivo. Currently no minimum strength requirement has been established for this test.

E. Lever-out Strength

28mm and 32mm liners were tested. The smallest shell sizes (48/37mm for the 28mm liners and 52/41mm for the 32mm liners) were used for testing. This is the worst case condition for testing because these devices have the least taper surface contact area within this acetabular system.

First, a hole was bored in the liner at an angle of approximately 25° to the horizontal. Then, the liner was assembled into the shell with a 2kN axial load with a feed rate of 15 N/sec applied by a ceramic ball head. The liner/shell assembly was mounted in the lever-out fixture and a load was applied by a lever arm through the hole at a feed rate of 2mm/min. The load required to cause the liner to slip was recorded, subject to a maximum load of 1kN. Failures in the fixture or the shell were recorded.

Pass/Fail Criteria

The lever-out strength values were greater than 30 Nm. Currently no minimum strength requirement has been established for this test.

F. Push-out Strength

28mm and 32mm liners were tested. The smallest shell sizes (48/37mm for the 28mm liners and 52/41mm for the 32mm liners) were used for testing. This is the worst case condition for testing because these devices have the least taper surface contact area within this acetabular system.

The liners were pressed into a metal shell with a bore in the backside. The liners were pushed in by a ceramic head with an axial load of 2kN with a feed rate of 15 N/sec. The assembly was then placed on a metal ring that only touches the outside metal shell. Load was applied by a punch going through the bore on the backside. The load at which the insert came loose from the metal shell was recorded.

Pass/Fail Criteria

The push-out strength was greater than the 200N minimum requirement per the CeramTec qualification procedure.

G. Ultimate Compressive Strength

28mm and 32mm liners were used for this testing. The smallest shell sizes (48/37mm for the 28mm liners and 52/41mm for the 32mm liners) were used for testing because these provide the highest stress conditions due to having the smallest cross sectional area.

Liners and metal shell inserts were assembled using a ceramic head with a 2kN load and a feed rate of 15 N/sec. The assembly was potted into the test fixture and load was supplied by a ceramic head until the liner fractured. The feed rate for the head was 2mm/min.

Pass/Fail Criteria

The average fracture strength was greater than 46kN and no liner had a fracture stress of less than 25kN which are the CeramTec pass criteria.

H. Fatigue Test

28mm liners were used for this testing. The smallest shell sizes (48/37mm for the 28mm liners) were used for testing because these provide the highest stress conditions due to having the smallest cross sectional area. This combination of the smallest insert liner and the smallest shell is considered the worst-case scenario. This assumption was verified by the Ultimate Compressive Strength test of the components.

Liners and metal shell inserts were assembled using a ceramic head with a 2kN load and a feed rate of 15 N/sec. Each assembly was then potted into a fixture using an aluminum-filled epoxy. Assemblies were placed in a tank containing Ringer's solution. A 1.4-14kN sinusoidal load was applied to each liner at a maximum rate of 25Hz using a ceramic head. Tests were conducted to 10 million cycles. Tested samples were examined for signs of cracking and then subjected to compressive strength tests in order to determine the residual post-fatigue strength.

Pass/Fail Criteria

Components showed no evidence of cracking or fracture after 10 million cycles at 1.4 -14kN and residual compressive strengths were greater than 25kN.

X. SUMMARY OF CLINICAL INVESTIGATIONS

As previously stated, the C^2a- Taper™ Acetabular System is similar to the previously approved TRANSCEND Ceramic Hip System (P010001). Biomet references the clinical data from P010001, under a licensing agreement, as clinical support for the safety and effectiveness of the C^2a- Taper™ Acetabular System. The clinical data are relevant because the ceramic acetabular inserts of the C^2a- Taper™ Acetabular System are identical to a subset of the ceramic acetabular inserts of the TRANSCEND system (P010001) and the ceramic femoral heads of the C^2a- Taper™ Acetabular System are identical to the ceramic femoral heads of the previously approved system. C^2a- Taper™ Acetabular System uses Biomet's own acetabular shells (designed to mate with the ceramic inserts) and a subset of Biomet's stems. The two systems were shown to perform similarly on the bench.

A. Published Literature

Published literature of early results of the Ceramic TRANSCEND® discuss significant improvement in average Harris Hip Scores and S-12 scores. No fractures of the ceramic components were reported in these articles.[1,2]

B. Pivotal Clinical Study

The Ceramic TRANSCEND® Hip Articulation System pivotal clinical study was approved on November 4, 1996 and the first patient was implanted with the investigational device on April 7, 1997.

The study was a prospective, multi-center, non-masked clinical trial, comparing the Ceramic TRANSCEND® Hip Articulation System to the historical control group of the Whiteside Total Hip System, which was approved in 1990. Patients are currently being followed until the last patient enrolled was seen for his/her two-year exam. Patients were implanted with the Ceramic TRANSCEND® Hip Articulation System and a commercially cleared Wright Medical hip system, including the following: BRIDGE®, PERFECTA®, EXTEND®, and Wright Choice Hip Systems.

Although the primary efficacy endpoint in the clinical study was the survivorship of the Ceramic TRANSCEND® Hip Articulation System as assessed at the two year postoperative interval, for the purpose of the clinical study, the primary efficacy endpoints included Harris Hip Score and radiographic assessments at 2 years, as well. In addition, patient satisfaction was assessed by the SF-12 at two years.

Complication rates were the primary safety endpoint.

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[1] Garino, Jonathan P., M.D. "Modern Ceramic-on-Ceramic Total Hip Systems in the United States." *Clinical Orthopedics and Related Research 2000; 379:41-47.*

[2] Murphy, Stephen B., M.D., and Wael K. Barsoum, M.D. "Ceramic-Ceramic Bearings in Total Hip Arthroplasty: Preliminary Clinical Results. "*The Orthopaedic Journal at Harvard Medical School 2001;3:92-94.*

Study Design

The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from Whiteside Total Hips System clinical trial consisting of non-inflammatory degenerative joint disease cases. Study patients consisted of individuals over 21 years of age presenting for total hip arthroplasty due to osteoarthritis, congenital hip dysplasia, traumatic arthritis and avascular necrosis. A total of 329 procedures have been performed with the Ceramic TRANSCEND® device in the original pivotal clinical population (Original Clinical Population). An additional 630 devices were implanted under Continued Access. The total number (Original Clinical Population and Continued Access) meeting the inclusion/exclusion criteria as required by the protocol is 959 procedures in 848 patients. Over a two-year period, 211 hip prostheses (179 patients) with metal femoral stems and plastic cups were implanted in the Whiteside Clinical Study.

Pivotal Clinical Patient Assessment

Each patient was evaluated at the immediate and 6, 12, and 24-month post-operative intervals, unless otherwise indicated by complications. At each follow-up visit, a Harris Hip Score and SF-12 was administered as well as obtaining AP and lateral radiographs. Radiographs were reviewed by the implanting surgeon. There were no pre-specified success/failure criteria in the pivotal clinical study.

Demographics

For the study population, there were a total of 965 procedures performed in 854 patients at 12 sites by 19 surgeons. Six of these patients did not meet study inclusion criteria (one procedure enrolled as a replacement for a previously implanted THR and five procedures performed in patients with rheumatoid arthritis). These six procedures are excluded from this analysis. Therefore, the primary analysis sample included 959 procedures for first hip replacements performed in 848 patients.

The patient accounting and Baseline Demographics are summarized in Tables 1 and 2. Note that there were 9 deaths, none of which were related to the study or to the device.

Table 1: Patient Accounting

Evaluation Interval	Original Clinical Patient Population (n=329)			Continued Access Population (n=630)		
	TFU	EFU	AFU(%)	TFU	EFU	AFU(%)
Pre-Op	329	329	A100% (n=329)	630	630	100% (n=630)
6 months	329	323	93% (n=300)	602	602	71% (n=430)
12 months	329	321	91% (n=293)	443	442	53% (n=233)

24 months	329	321	94% (n=302)	151	150	0% (n=0)

TFU = Theoretical Follow-Up
EFU = Expected Follow-Up (Theoretical Follow-Up minus deaths and removals without replacement)
AFU = Actual Follow-up

Table 2: Baseline and Demographics

Values	Total Study Procedures (n=959)	Whiteside Clinical Study (n=211)
Mean Age in Years	51.4 Years (range 20-80)	62.7 years (range 22-87)
Gender	595 (62%) Males 364 (38%) Females	112 (53%) Males 99 (47%) Females
Mean Body Mass Index (kg/m^2)	28.8 (range 17.7-65.8)	27.1 (range 22.8-40.9)
Diagnosis		
Osteoarthritis	692 (72.2%)	180 (85.3%)
Avascular Necrosis	189 (19.7%)	31 (14.7%)
Traumatic Arthritis	36 (3.8%)	0
Congenital Hip Dysplasia	42 (4.4%)	0
Mean Baseline Total HHS (range 1-100)	45.1 (range 8.3-95.9)	42.7 (range 11-79)
Mean Baseline Pain HHS (range 0-44)	12.9 (range 0-44)	13.2 (range 0-30)
Mean Baseline Harris ROM° (range 0-5)	3.8 (range -3.1-4.88)	4.1 (range not available)

Safety and Effectiveness Data

Adverse Events

The adverse events related to total hip replacement surgery reported in the clinical study including 959 patients are listed in Table 3.

Table 3: Reported Adverse Events

Event	Clinical Study (n=959)		Whiteside Clinical Study (n=211)	
Systemic	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Deaths	9	0.9%	0	0%
Pulmonary Embolism	2	0.2%	2	0.9%
Deep Vein Thrombosis	4	0.4%	0	0%
Local	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Revisions/Removals[1]	11	1.1%	8	3.8
Breakage/Fracture of Component[2]	5	0.5%	2	0.9%
Dislocation (single) of Component[3]	8	0.8%	3	1.4%
Dislocation (recurrent) of Component[4]	2	0.2%	0	0%
Femoral Fracture	18	1.9%	9	4.3%
Hematoma	2	0.2%	0	0%

Heterotopic Ossification	1	0.1%	1	0.5%
Infection: Deep, Early <1 year	2	0.2%	0	0%
Infection: Deep, Late > 1 year	1	0.1%	0	0%
Infection: Superficial	7	0.7%	0	0%
Loosening of Component	3	0.3%	2	0.9%
Migration of Component	2	0.2%	0	0%
Persistent Foot Drop	2	0.2%	0	0%
Pain	10	1.0%	0	0%
Perforation of Femur During Reaming	2	0.2%	0	0%
Wear of Component	1	0.1%	0	0%
Subsidence of Component	3	0.3%	2	0.9%
Soft Tissue Trauma	0	0%	0	0%
Wound Problems	2	0.2%	0	0%
Other Local Complication[5]	10	1.0%	0	0%
Local-Hip	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

Notes:

[1] See details in the following Table 9 for n=959

[2]Clinical Study: Chipping of ceramic acetabular liner during placement requiring intraoperative revision.

Whiteside Clinical Study: Broken metal peg of acetabular cup.

[3]2 were revised for this reason.

[4]1 was revised for this reason.

[5]Consisted of: 3 cases of irritation/inflammation; 2 cases where patients fell; 1 case of component mismatch; 1 case of liner malposition; 1 case where the acetabular shell seated too deeply in the reamed cavity; 1 case of hip flexor weakness; and 1 case where the anterior abductor pulled off.

Revisions and Removals

Eleven devices out of the 959 primary patients enrolled in the trial have been revised or removed. Table 4 summarizes the clinical information pertaining to these cases.

Table 4: Summary of Revisions and Removals

Procedures	**Age/ Gender**	**Diagnosis**	**Duration of Implantation**	**Reason for Revision/Removal**
Revision of acetabular Component with bone graft and cage implantation	50/F	AVN	84 days	Migration of acetabular component
Revision of femoral head	29/F	Congenital Hip	1 day	Dislocation

With a longer neck		Dysplasia		
Replaced acetabular component to larger size (32mm) and replaced femoral head to 35mm	43/M	Severe osteoarthritis with mild hip dysplasia	1 day	Dislocation
Replacement of acetabular component, liner, and femoral head. Repair of abductor mechanism.	62/M	Osteoarthritis	38 days	Persistent dislocation following closed reduction, trochanteric fracture with avulsion of abductors.
Revision followed by removal and Girdlestone procedure	51/M	Traumatic arthritis	210 days	Deep infection and stitch abscess
Replacement of acetabular liner	36/F	Congenital hip dysplasia	3 days	Acetabular liner disassociated from shell
Replacement of acetabular liner and femoral head	41/M	Osteoarthritis	14 days	Increasing pain, suspected infection
Replacement of acetabular liner and femoral head	58/M	Avascular Necrosis	953 days	Excessive wear due to impingement on acetabular cup rim
Replacement of femoral head from 32mm to 28mm	50/M	Osteoarthritis	1 day	Liner/head size mismatch noted on postoperative film
Replacement of (uncemented) femoral stem to cemented stem	56/M	Osteoarthritis	657 days	Pain and progressive subsidence due to undersized (uncemented) femoral stem
Replacement of femoral stem and head	56/F	Osteoarthritis	786	Femoral component loosening

Efficacy results

Table 5, below, shows the mean and range of Harris Hip Scores for each study cohort preoperatively and two years postoperatively

Table 5: Efficacy Results--HHS

Primary Efficacy Assessment	Original Patient Population (n=329)[1]	Continued Access Population (n=630)[2]	Whiteside Clini Study (n=211
Preoperative mean HHS (range)	44.8 (13-89)	45.2 (8-96)	42.7 (11-79)
2 year postop mean HHS (range)	94.8 (34-100)	88.1 (17-100)	92.7 (39-100)

% Excellent/Good Results (HHS 80-100 points) at 2 years postop	92.2%	76.9%	88.2%

Notes:

[1] Original clinical study population includes the first 329 procedures enrolled in the pivotal clinical study. This includes replacements and removals prior to 24 months (n=9), death prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)

[2] The *Continued Access* sample (N=630) includes procedures performed after the original population without Month 24+ outcomes. Therefore, outcomes reported were defined on the basis of Last Observation carried Forward (LOCF) and represent the latest clinical results available for that procedure.

Any Radiographic Lucency

Radiolucencies were recorded at each follow-up visit based on if they involved the entire Gruen zone (7 AP femoral zones, 7 lateral femoral zones, 3 AP acetabular zones, and 3 lateral acetabular zones). Table 6 summarizes these results.

Table 6: Any Radiolucency

Lucency	Original Study Population (n=329)	Whiteside Clinical Study (n=211)
Femoral	18 (5.5%)	66 (31.3%)
Acetabular	9 (2.8%)	56 (26.5%)
Overall	22 (6.8%)	77 (36.5%)

In addition, any subsidence was reported for the original study population for 0.9% of the femoral stems and 0.3% of the acetabular cups. In the Whiteside Clinical Study there were two instances of femoral stem subsidence (1.0%).

Implant Survivorship

Implant survivorship was the pre-specified primary endpoint in the pivotal clinical study of the Ceramic TRANSCEND® hip. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the Ceramic TRANSCEND® and the Whiteside hips over time.

The cumulative Kaplan-Meier survivorship values for the femoral or acetabular component are shown in Tables 6 and & based on the longest duration of follow-up available in each study cohort.

Table 7: Ceramic TRANSCEND® Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	528	69	8	0.9909	0.0041
24 months	279	78	1	0.9876	0.0066
36 months	1	0	0	0.9876	0.0562

Table 8: Whiteside Clinical Study Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	234	8	3	0.9870	0.0074
34 months	223	70	1	0.9817	0.0090
36 months	152	103	1	0.9719	0.0131
48 months	48	34	3	0.8779	0.0481
60 months	11	11	0	0.8779	0.0481

Patient Success Criteria

Table 9 describes the proportion of patients meeting individual clinical success criteria at 2 years postoperatively.

Table 9: Patient Success Criteria at 2 Years

Patient Success Criteria	Original Patient Population (n=329)[1]	Whiteside Clinical Study (n=211)
Absence of Revision (5)	96.7% (n=318)	98.1% (n=207)
Total HHS > 70	96.8% (n=318)	95.3% (n=201)
No Complete Radiolucencies[2]	99.7% (n=328)	88.5% (n=184)

Notes:

[1] The *Original Patient Population* sample includes procedures in the *Complete Endpoint* (N=309) sample plus procedures with revisions, replacements, or removals prior to Month 24 (N=9); who died prior to Month 24 (N =7); or who had only a partial Harris Hip Score assessment at Month 24 or later (N=4). This sample was constructed in order to facilitate an analysis of efficacy and safety endpoints for hips that were at-risk for a complication and that 'completed the study.' *For Complete Follow-up* procedures (N=329), the Month 24+ endpoint was defined as the Month 24 value and if not available, value after Month 24 were used. Original pivotal clinical population includes the first 329 procedures enrolled in the clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7) and cases in which only a partial Harris Hip score at 34 months or later was available (n=4).

[2] Absence of complete radiolucency were determined by radiographic evaluation for four views: acetabular AP view (3 regions), acetabular lateral view (3 regions) femoral stem AP view (7 regions), and femoral stem lateral view (7 regions). Complete radiolucency in a view was defined to be present if there was any radiolucency present in all zones comprising that view. Absence of complete radiolucency was defined to be present if none of these four views had complete radiolucency.

XI. STUDY CONCLUSIONS

The pre-clinical and referenced clinical data provide reasonable assurance that the C^2a-Taper™ Acetabular System is safe and effective for total hip replacement in patients with osteo/degenerative arthritis, avascular necrosis, and related diagnoses.

A system comparison analysis between the C^2a-Taper™ Acetabular System and the referenced ceramic hip system (P010001) was performed to demonstrate that the systems perform similarly enough on the bench that the clinical data referenced above can be used to predict the clinical outcomes for the C^2a-Taper™ Acetabular System.

Therefore, based on information contained in this PMA and P010001 it is reasonable to conclude that the benefits of theC^2a-Taper™ Acetabular System for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use.

XII. PANEL RECOMMENDATIONS

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA application was not referred to the Orthopedic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

FDA issued an approval order on December 16, 2005

The conditions of approval require a 10-year post-approval study to evaluate the long term safety and effectiveness of the C^2a-Taper™ Acetabular System. The study will enroll a minimum of 257 patients, of whom a minimum of 160 patients will be followed to 5 years and a minimum of 100 patients will be followed out to 10 years. During the first 5 years, clinical, radiographic, and subject self-assessment information will be collected for each patient. For the sixth through tenth postoperative years, patients will be asked to return an outcomes questionnaire designed to determine the status of their hip replacement.

The applicant's manufacturing facilities were inspected and determined to be in compliance with the Quality System Regulation (21 CFR Part 820).

XIV. APPROVAL SPECIFICATIONS

Directions for Use: See the Device Labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the label

Post-Approval Requirements and Restrictions: See Approval Order